APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: John D. Hatlestad et al.	Examiner: Sheetal R. Rangrej
Serial No.: 10/787,045	Group Art Unit: 3686
Filed: February 25, 2004	Docket: 279.B27US1

Title: ADVANCED PATIENT AND MEDICATION THERAPY MANAGEMENT SYSTEM AND METHOD

APPEAL BRIEF UNDER 37 CFR § 41.37

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P.O. Box 1450
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The Appeal Brief is presented in response to the Notice of Panel Decision from Pre-Appeal Brief Review mailed on July 20, 2009 and further in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on July 1, 2009, from the Final Rejection of claims 1-11, 13-14, and 16-28 of the above-identified application, as set forth in the Final Office Action mailed on April 1, 2009.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $540.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, CARDIAC PACEMAKERS, INC., which is a subsidiary of BOSTON SCIENTIFIC CORP.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

In accordance with 37 CFR 41.37(c)(1)(iii) requiring a statement of the status of all claims, pending and canceled, Appellant submits the following:

The present application was filed on February 25, 2004 with claims 1-28. A Non-Final Office Action was mailed October 9, 2007. In the response filed March 10, 2008, claim 15 was canceled. A Final Office Action was mailed June 11, 2008. In response, claim 12 was canceled in the Amendment and Response filed with the Request for Continued Examination on September 11, 2008. A Non-Final Office Action was mailed September 30, 2008. A Final Office Action was mailed April 1, 2009. A decision on a Pre-Appeal Brief was mailed July 20, 2009. Claims 1-11, 13, 14, and 16-28 stand twice rejected, remain pending, and are the subject of the present Appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action mailed April 1, 2009.

5. SUMMARY OF CLAIMED SUBJECT MATTER

This summary is presented in compliance with the requirements of Title 37 C.F.R. § 41.37(c)(1)(v), mandating a "concise explanation of the subject matter defined in each of the independent claims involved in the appeal …". Nothing contained in this summary is intended to change the specific language of the claims described, nor is the language of this summary to be construed so as to limit the scope of the claims in any way.

Aspects of the present inventive subject matter include, but are not limited to, advanced patient and medication therapy management systems and methods.

INDEPENDENT CLAIM 1 (see, e.g., FIGS. 1, 3, and 4; page 5, line 27 through page 16, line 11)

Some of the embodiments claimed are related to a medication storage, therapy and consumption management system (100) comprising an implantable device (102, 104, 105, or 106) configured to implantably electrically monitor fluid retention. An external, non-ambulatory containment unit (260) is configured to accessibly house diuretic medication. A health management host system (112) is coupled to the containment unit in a manner that allows data transmission. The containment unit includes a communications and control system (211) that records and transmits data relating to a medication event. The containment unit control system further provides for transmitting and receiving medication therapy data. The health management host system is configured to receive data related to the medication event, receive patient physiological data including fluid retention data collected by the implantable device, analyze the patient physiological data and the medication event data, and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data.

INDEPENDENT CLAIM 9 (see, e.g., FIGS. 1, 3, and 4; page 5, line 27 through page 16, line 11)

Some of the embodiments claimed are related to an electronic patient health management system (100) comprising an implantable medical measurement device (102, 104, 105, or 106) for implantably electrically measuring data related to at least one patient physiological health factor

including fluid retention data. An external, non-ambulatory medication therapy management device (260) is configured to house diuretic medication and store data related to patient consumption of medication. The medication therapy management device is further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement device and the data related to patient consumption of medication. A patient wellness host system (112), communicatively coupled to the medication therapy management device, is configured to receive the processed data and use the processed data to generate a diuretic medication therapy regimen.

INDEPENDENT CLAIM 24 (see, e.g., FIGS. 1 and 3; page 5, line 27 through page 16, line 11)

Some of the embodiments claimed are related to a method for remote management of a medication therapy using an external, non-ambulatory medication containment unit (260), the method comprising alerting a patient when it is time to carry out a diuretic medication step of a first therapeutic plan. Engagement of the external, non-ambulatory medication containment unit is sensed and recorded as a medication event. Fluid retention data is implantably electrically sensed. Patient physiological data including the implantably-sensed fluid retention data is received. The patient physiological data and the medication event data are processed. A second therapeutic plan is generated in response to the processing of the patient physiological data and the medication event data.

The above summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers the Board to the appended claims and their legal equivalents for statements of invention in the instant application. Page and line numbers and reference symbols from the drawing are exemplary in nature. Further, these page and line numbers are not intended to be an exhaustive listing of each and every location where the particular subject matter can be found in the specification.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-11, 13-14, and 16-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yarin et al. (U.S. Patent No. 6,294,999) in view of LaPorte et al. (U.S. Patent Application Publication No. 2005/0182389).

7. ARGUMENT

A) The Applicable Law

A.1. Standard of Review

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.

After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

If examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent."[1]

A.2. The Applicable Law under 35 U.S.C. §103(a)

The determination of obviousness requires that the Examiner meet his or her burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness.[2] As discussed by the U.S. Supreme Court in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), the determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence.[3] The legal conclusion, that a claim is obvious within § 103(a), depends on at least four underlying factual issues set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations.

In combining prior art references to construct a *prima facie* case, the Examiner must show some objective evidence in the prior art or some knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant portions of the

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[1] *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992)(citations omitted); *see In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).
[2] *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).
[3] *See Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1336-37, 75 USPQ2d 1051 (Fed. Cir. 2005).

references.[4] However, the level of skill is generally that of the person who follows the conventional wisdom in the art.[5] An invention can be obvious even though the reason to combine prior art teachings is not found in a specific reference.[6] But the requirement of some reason to combine references in a *prima facie* case of obviousness is emphasized in the Federal Circuit opinion, *In re Lee*,[7] which notes that the reason must be supported by some evidence in the record.

The *KSR* Court merely rejected a rigid application of any "teaching, suggestion, motivation" test; it recognized that a more flexible conception of the test is entirely consistent with the *Graham* analysis.[8] The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention.[9] References must be considered in their entirety, including parts that teach away from the claims.[10] The fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.[11]

Notably, the *KSR* Court affirmed that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." [12] The Examiner must, as one of the inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103, recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art.[13] Moreover, when a reference teaches away from a claimed invention, this fact highly probative that the reference would not have rendered the claimed invention obvious to one of ordinary skill in the art.[14] If the proposed modification or

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[4] *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).
[5] *Standard Oil Co. v. American Cyanamid Co.,* 774 F.2d 448, 454, 227 USPQ 293, 298 (Fed. Cir. 1985).
[6] *See In re Oetiker*, 977 F.2d 1443, 1448, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992).
[7] *In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).
[8] *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401, 127 S.Ct. 1727, 1731 (2007).
[9] *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985).
[10] *See* M.P.E.P. § 2141.02.
[11] *See generally In re Mills*, 916 F.2d 680, 16 USPQ2d 1430, 1432-1433 (Fed. Cir. 1990); M.P.E.P. § 2143.01.
[12] *See In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1335-1336 (CA Fed. 2006) (cited with approval in *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-41 (2007)).
[13] *See In re Bond, 910* F.2d 831,834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh'g denied,* 1990 U.S. App. LEXIS 19971 (Fed. Cir.1990).
[14] *Stranco Inc. v. Atlantes Chemical Systems, Inc.*, 1990 WL 10072072, 15 USPQ2d 1704, 1713 (Tex. 1990).

combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.[15] The CCPA has also noted that "[t]he court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is, we must view the prior art without reading into that art appellant's teachings."[16] Thus, these principles have not been changed by the ruling in *KSR*.

B. Discussion of the Rejection

B.1. Discussion of the rejection of 1-11, 13-14, and 16-28 under 35 U.S.C. § 103(a) as being unpatentable over Yarin et al. (U.S. Patent No. 6,294,999) in view of LaPorte et al. (U.S. Patent Application Publication No. 2005/0182389).

Appellant requests reversal of the rejection of claims 1-11, 13, 14, and 16-28 because of clear error in that a proper *prima facie* case of obviousness has not been established.

1. There is no motivation to combine Yarin et al. and LaPorte et al.

No *prima facie* case of obviousness presently exists for these claims because there would be no objective reason to combine Yarin et al. with LaPorte et al. The Final Office Action, dated April 1, 2009 (hereinafter, "the Office Action"), at page 3 admits that "Yarin . . . fails to expressly teach a medication storage, therapy, and consumption management system, comprising: an implantable device configured to implantably electrically monitor fluid retention; and receiving patient physiological data including fluid retention data collected by the implantable device." However, the Office Action at page 3 contends that "LaPorte teaches a medication storage, therapy, and consumption management system, comprising: an implantable device configured to implantably electrically monitor fluid retention; and receiving patient physiological data including fluid retention data collected by the implantable device". The Office Action further contends at page 3 that "[o]ne of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Yarin with the teachings of LaPorte with the motivation that therapeutic substance therapy in conjunction with the activities

[15] *See generally In re Ratti*, 270 F.2d 810, 123 USPQ 349, 352 (CCPA 1959).
[16] *In re Sponnoble,* 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969).

and information obtained by an implanted medical device is an important consideration in the overall treatment of a patient".

Yarin et al. relates to a *completely external, non-ambulatory system*. That is, the Smart Tray 12 of Yarin et al. is an externally disposed medication dispenser, and the appliances listed in Yarin et al. with which the Smart Tray 12 can communicate are external devices including "personal computers 22a, Web TVs 22b, weight scales 22c, refrigerators 22d, exercise devices 22e, and scanners 22f." (Yarin et al. at col. 5, lines 53-54.) The Smart Tray 12 further includes "a receptacle that is configured to removably receive and interact with various objects . . . [such as] blood pressure monitors, thermometers, pagers, glucometers, prothrombin and coagulation monitors." (Yarin et al. at col. 6, lines 39-44.) Again, all the listed devices intended to be used with the Smart Tray 12 of Yarin et al. are external devices. Yarin et al. states that "[a] Smart Tray according to the present invention passively and unobtrusively facilitates monitoring patient compliance with medication treatment regimens." (Yarin et al. at col. 9, lines 63-65.) There is no description in Yarin et al. related to use with internal devices, as acknowledged by the Office Action.

In contrast, LaPorte et al. relates to an *ambulatory, internal system*. LaPorte et al. describes a "device [that] delivers a therapeutic substance to the patient *while allowing the patient to remain mobile*." (LaPorte et al. at page 1, paragraph [0007] (Emphasis added).) LaPorte et al. further states that "a medical therapy system includ[es] an implanted medical device 30 and a patch 32 for attachment to the skin of a patient." (LaPorte et al. at page 2, paragraph [0041].)

There is simply no objective reason to combine the *non-ambulatory system* of Yarin et al. with the *ambulatory system* of LaPorte et al. LaPorte et al. relates to a system that *allows the patient to remain mobile* while delivering a therapeutic substance. Yarin et al. relates to an *external, non-ambulatory system for passively and unobtrusively* facilitating monitoring of patient compliance with medication treatment regimens. One of ordinary skill in the art would not look to the ambulatory system of LaPorte et al. to modify the non-ambulatory system of Yarin et al. In fact, Yarin et al. teaches away from being combined with LaPorte et al. and vice versa. There is simply no way to *passively and unobtrusively* monitor patient compliance with medication treatment regimens using an implanted device, nor is there any way to *allow the*

patient to remain mobile while delivering a therapeutic substance using the external, home-based Smart Tray system of Yarin et al. Appellant submits that, short of improper hindsight reconstruction, there is no reason and no objective reason to combine the passive, unobtrusive Yarin et al. medication monitoring system with the mobile medical therapy system of LaPorte et al. The Office Action at page 9 goes on to contend that "any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning" and that "such a reconstruction is proper" if it "does not include knowledge gleaned only from the applicant's disclosure". However, short of improper hindsight reconstruction of Appellant's claims, one of ordinary skill would not look to the *internal system* of LaPorte et al. to modify the *completely external system* of Yarin et al.

The Office Action at page 9 contends that "the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." However, the Office Action stops there and does not then go on to offer any possible objective reason for the proposed combination, presumably relying on the contention at page 3 of the Office Action that "the motivation that therapeutic substance therapy in conjunction with the activities and information obtained by an implanted medical device is an important consideration in the overall treatment of a patient". Contending that something is an "important consideration" does not amount to an objective motivation and is nothing more than a baseless statement. While the Appellant appreciates that the Examiner recognizes that obviousness can only be established where there is some objective reason to combine the references in the manner suggested, Appellant takes the Office Action's silence as to actual reason as further evidence that no objective reason exists for the combination of Yarin et al. and LaPorte et al. proposed by the Office Action.

In sum, because the proposed combination of references lacks any objective reason for their combination by one of ordinary skill in the art, Appellant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. The rejection constitutes clear error and should be reversed

2. The proposed combination of Yarin et al. and LaPorte et al. would not function

Even assuming, for the sake of argument, that the references were combined in the manner proposed by the Office Action, the proposed combination would not function. There is no indication in Yarin et al. that the Smart Tray 12 is configured to communicate with an implanted sensor. In fact, Yarin et al. includes "a receptacle that is configured to removably receive and interact with various objects . . . [such as] blood pressure monitors, thermometers, pagers, glucometers, prothrombin and coagulation monitors." (Yarin et al. at col. 6, lines 39-44.) Of course, the implanted device of LaPorte et al. would be incapable of being received within such a receptacle of Yarin et al. While Yarin et al. does state that wireless communications may be used for the devices of Figs 1 and 2 (*see* Yarin et al. at col. 6, lines 1-5; and Figs 1 and 2), none of the devices shown or described by Yarin et al. are *implanted* within a patient. Moreover, wireless communication of the *external, non-ambulatory* Yarin et al. Smart Tray with a stationary weight scale, for instance, is not akin to wirelessly communicating with a mobile implanted device within a patient. The present application solves numerous problems and technical challenges to allow communication between an external containment unit and an implantable device that Yarin et al. and LaPorte et al., either alone or in combination, do not even address. The Office Action fails to grasp this point, as is evidenced by the contention of the Office Action at page 9 that "Yarin is only distinguished from LaPorte in the sense that it communicates with an external device." For instance, Yarin et al. includes no description related to a structure, module, etc. for proximity detection and synchronization of the Smart Tray of Yarin et al. with any mobile, implanted device, such as the implanted device of LaPorte et al., in order to allow for communication therebetween, as would be necessary for the proposed modified device to function. Likewise, LaPorte et al. includes no description related to a structure, module, etc. for proximity detection and synchronization of the implanted device of LaPorte et al. with the external Smart Tray of Yarin et al., in order to allow for communication therebetween, as would be necessary for the proposed modified device to function. As such, even if the references were combined in the manner suggested by the Office Action, the resulting combination would be unable to overcome the numerous problems and technical challenges identified above and would, therefore, not function to provide communication between the non-ambulatory Smart Tray of Yarin et al. and the ambulatory implanted device of LaPorte et al.

In sum, because the proposed combination of references is apparently non-functional, Appellant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. The rejection constitutes clear error and should be reversed.

SUMMARY

For the reasons explained above, claims 1-11, 13-14, and 16-28 were not properly rejected under 35 U.S.C. §103(a) as being unpatentable over Yarin et al. (U.S. Patent No. 6,294,999) in view of LaPorte et al. (U.S. Patent Application Publication No. 2005/0182389), and the rejection of these claims constitutes clear error. It is respectfully submitted that these documents do not render the claims obvious.

Therefore, Appellant respectfully requests reversal of the rejection of the pending claims and submit that the pending claims are in condition for allowance. If necessary please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402

Date August 31, 2009 By /Michael P. Horvath/
Michael P. Horvath
Reg. No. 57,235

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 31st day of August 2009.

Kate Gannon / Kate Gannon /

Name Signature

8. CLAIMS APPENDIX

1. A medication storage, therapy and consumption management system, comprising:

an implantable device configured to implantably electrically monitor fluid retention;

an external, non-ambulatory containment unit configured to accessibly house diuretic medication; and

a health management host system coupled to the containment unit in a manner that allows data transmission,

said containment unit including a communications and control system that records and transmits data relating to a medication event, said containment unit control system further providing for transmitting and receiving medication therapy data;

said health management host system configured to receive data related to the medication event, receive patient physiological data including fluid retention data collected by the implantable device, analyze the patient physiological data and the medication event data, and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data.

2. The system of claim 1, wherein the patient physiological data comprises weight and neuro-hormonal data.

3. The system of claim 1, wherein the containment unit is further configured to communicate wirelessly with said health management host system.

4. The system of claim 1, wherein the containment unit is configured with a display device to display the diuretic medication therapy regimen.

5. The system of claim 4, wherein the containment unit is configured to receive data from an external source and further configured to transmit such data to the health management host system.

6. The system of claim 1, wherein the containment unit is further configured to notify the patient when it is time to take the medication housed therein.

7. The system of claim 1, wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level.

8. The system of claim 1, wherein said health management host system processes said data related to the medication event data and said patient physiological data in response to the diuretic medication therapy regimen, and in response thereto provides for the generation of an updated diuretic medication therapy regimen.

9. An electronic patient health management system, comprising:

an implantable medical measurement device for implantably electrically measuring data related to at least one patient physiological health factor including fluid retention data;

an external, non-ambulatory medication therapy management device, configured to house diuretic medication and store data related to patient consumption of medication, the medication therapy management device further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement device and the data related to patient consumption of medication; and

a patient wellness host system, communicatively coupled to the medication therapy management device, configured to receive the processed data and use the processed data to generate a diuretic medication therapy regimen.

10. The system of claim 9, wherein the medication therapy management device is further configured to provide a reminder to a patient when it is time to take the medication.

11. The system of claim 9, comprising an external medical measurement device for measuring data related to at least one patient physiological health factor.

13. The system of claim 9, wherein the medical measurement device is communicatively coupled to the patient wellness host system via an Internet connection.

14. The system of claim 9, wherein the medical measurement device is communicatively coupled to the patient wellness host system via a wireless communication link.

16 The system of claim 9, wherein data related to the at least one patient physiological health factor comprises data monitored by an implantable device.

17. The system of claim 9, wherein data related to the at least one patient physiological health factor comprises weight data.

18. The system of claim 9, wherein data related to the at least one patient physiological health factor comprises neuro-hormonal data.

19. The system of claim 9, wherein data related to the at least one patient physiological health factor comprises renal function data.

20. The patient wellness host system of claim 9 further configured to process said data received in order to develop a therapeutic response.

21. The system of claim 20, wherein the developed therapeutic response comprises revising medication regime, maintaining current medication regime, and recommending a diet plan.

22. The system of claim 9, wherein the patient wellness host system is a computer, which comprises with a memory, a processor and a user interface.

23. The system of claim 9, wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level.

24. A method for remote management of a medication therapy using an external, non-ambulatory medication containment unit, the method comprising:

alerting a patient when it is time to carry out a diuretic medication step of a first therapeutic plan;

sensing when the external, non-ambulatory medication containment unit is engaged and recording the same as a medication event;

implantably electrically sensing fluid retention data;

receiving patient physiological data including the implantably-sensed fluid retention data;

processing said patient physiological data and said medication event data; and

generating a second therapeutic plan in response to said processing of said patient physiological data and said medication event data.

25. The method of claim 24, wherein the alerting step comprises notifying the patient to consume at least one of medication and food.

26. The method of claim 24, wherein the alerting step comprises causing the external, non-ambulatory medication containment unit to generate one of the following, an audible sound, to vibrate and to communicate with a second external device which responsively prompts the patient to act.

27. The method of claim 24, wherein the receiving step is initiated by an external device transmitting patient physiological data to the external, non-ambulatory medication containment unit.

28. The method of claim 24, wherein the receiving step is initiated when the external, non-ambulatory medication containment unit interrogates an external device.

9. EVIDENCE APPENDIX

None.

10. RELATED PROCEEDINGS APPENDIX

None.